

REMARKS

Applicants wish to thank the Examiner for the review of the present application. Applicants have amended claims 1, 7, 10, 18, 20-22, 55-61, 66 and 85-86. Applicants have also added new claims 94-227. Further, claims 2-6, 8-9, 11-14, 16-17, 23-54, 62-65, 72-84 and 87-93 have been cancelled. Claims 1, 7, 10, 15, 18-22, 55-61, 66-71, 85-86 and 94-227 are now pending in the application. No new matter has been added.

Claim Objections

The Office Action objects to claims 1, 3-22 and 34-93 for various informalities, such as improper antecedent basis or extraneous punctuation. Applicants believe the various informalities have been corrected in the now pending claims. In claim 1, the phrase “said joint” has been changed to “a joint.” In claim 10, the extraneous comma has been removed. In claim 18, the proper article has been added. As noted above, the remaining claims discussed in the Office Action, claims 3-6, 8-9, 11-14, 16-17, 34-35, 42-44, 46, 62-63, 82, 84, 87 and 93, have been cancelled.

Accordingly, Applicants believe the claim objections are now moot.

Double Patenting

The Office Action rejects claims 1, 3-22 and 34-93 on the basis of non-statutory obviousness-type double patenting over claims 94-293 of U.S. Patent No. 7,239,908 and claims 1-44 of U.S. Patent No. 7,184,814. To address these rejections, Applicants herewith provide a terminal disclaimer. Applicant’s submission of this terminal disclaimer should not be construed as an admission that the present claims are obvious in view of the listed claims of the identified patents.

The Office Action also provisionally rejects claims 1, 3-22 and 34-93 on the same basis over claims 1-120 of co-pending Application No. 11/769,434; claims 69-72 and 75-89 of co-pending Application No. 09/882,363; claims 1-114 of co-pending Application No. 11/739,326; claims 1-16 of co-pending Application No. 11/678,763; and claims 1-23 of co-pending Application No. 11/410,515. To address these rejections, Applicants herewith provide a terminal disclaimer. Applicant’s submission of this terminal disclaimer should not be construed as an

admission that the present claims are obvious in view of the listed claims of the identified patent applications.

35 U.S.C. § 112, ¶ 2

The Office Action rejects claims 1 and 3-9 as indefinite because the preamble refers to cartilage, but the body of the claim refers to cartilage and subchondral bone. The claims have been amended—the phrase “involving cartilage” has been deleted from the preamble of claim 1 and, by extension, from its dependent claims 3-9.

In addition, the Office Action rejects claims 1, 3-22 and 34-86 as indefinite because the claims are directed to a method of treating, but no steps of treatment have been positively recited. The preambles of independent claims 1 and 10 have been amended to read “a method of determining a therapy for joint disease” to more particular point out the subject matter Applicants regard as their invention. By extension, the remaining claims, which depend from either claim 1 (claims 7 and 55-61) or claim 10 (claims 15, 18-22, 66-71 and 85-86) have been similarly amended. As noted above, the remaining claims, claims 2-6, 8-9, 11-14, 16-17, 34-54, 62-65 and 72-84 have been cancelled.

Accordingly, Applicants believe the § 112, ¶ 2 rejections are now moot.

35 U.S.C. §103(a)

The Office Action rejects claims 1, 3, 5, 7, 10-11, 13, 15, 34-36, 48-50, 62-63, 79 and 87-93 as unpatentable over U.S. Patent No. 5,682,886 (Delp et al., hereinafter “Delp”) in view of U.S. Patent Number 6,161,080 (Aouni-Ateshian et al., hereinafter “Aouni-Ateshian”) and U.S. Patent No. 5,320,102 (Paul et al., hereinafter “Paul”). As noted above, Applicants have cancelled claims 3, 5, 11, 13, 34-36, 48-50, 62-63, 79 and 87-93. Thus, Applicants discuss this rejection only with regard to claims 1, 7, 10 and 15.

Claim 1 defines, in part, a method for determining therapy for joint disease including electronically deriving information on the thickness or shape of at least one of articular cartilage and subchondral bone to determine at least a portion of the geometry of an implant. The articular cartilage includes normal and/or diseased articular cartilage. At least a portion of the implant has a thickness similar to the thickness of normal articular cartilage adjacent to diseased articular

cartilage.

Delp fails to teach such a method. Rather, Delp discloses a method for planning surgery on an anatomical joint. In particular, Delp obtains image data of a patient's leg and then generates a three-dimensional computer model of the bones. Delp, col. 8, lines 32-65. After some additional processing, Delp uses the data to determine the femoral mechanical axis and the tibial mechanical axis, which are, in turn, used to determine proper limb alignment—data useful in planning surgical procedures.

The Office Action suggests that Delp teaches the use of the above-described information to “plan the design” of an implant. Applicants respectfully disagree. Delp is merely able to select an appropriate implant (*e.g.*, the size and pose) from a set of pre-identified implants. In other words, Delp merely selects an implant from a list of pre-set implant sizes, which must be loaded into the system. Delp does not teach or suggest the use of its computer model to determine at least a portion of the geometry of an implant. Delp also does not teach or suggest anything related to the thickness of normal and/or diseased articular cartilage. Further, Delp does not teach or suggest anything related to the thickness of an implant, let alone an implant having a thickness similar to the thickness of normal articular cartilage adjacent to diseased articular cartilage. Delp simply uses its computer model to determine biomechanical data, such as joint center data, the femoral mechanical axis, and the tibial mechanical axis—not the geometry of an implant or a portion of an implant.

Aouni-Ateshian and Paul fail to teach the deficiencies in Delp. Like Delp, Aouni-Ateshian discloses a method of generating a three-dimensional computer model of an anatomical joint and a method for planning surgery for the joint. Although its computer model includes representations of articular surfaces, Aouni-Ateshian does not teach or suggest the use of its computer model to determine at least a portion of the geometry of an implant, including at least a portion of its thickness. Rather, Aouni-Ateshian simply notes that “investigators have reconstructed cartilage topography and thickness from MR images.” Aouni-Ateshian, col. 38, lines 10-11. However, there is no teaching or suggestion related to the thickness of normal and/or diseased articular cartilage. Also, there is no teaching or suggestion related to the thickness of an implant, let alone an implant having a thickness similar to the thickness of normal articular cartilage adjacent to diseased articular cartilage.

Paul also does not teach or suggest a method to determine a therapy for joint disease, such method including, in part, electronically deriving information on the thickness or shape of at least one of articular cartilage and subchondral bone to determine at least a portion of the geometry of an implant with at least a portion of the implant having a thickness similar to the thickness of normal articular cartilage adjacent to diseased articular cartilage. Rather, Paul teaches a method for diagnosing proteoglycan deficiency in cartilage based on an MR image. In particular, Paul receives image data at a workstation and a user chooses a region of interest. Paul then records the gray-scale illumination representative of the MR signal intensity of individual pixels selected by the user. The pixel intensities may be processed (*i.e.*, averaged or interpolated) and plotted. Paul, col. 5, lines 1-40.

Claim 10 defines, in part, a method for determining therapy for joint disease including electronically deriving information on the thickness of articular cartilage, including normal and/or diseased articular cartilage, and selecting or designing a therapy wherein such therapy is an implant. As discussed above, neither Delp, Aouni-Ateshian, nor Paul teach or suggest anything related to the thickness of normal and/or diseased articular cartilage.

Therefore, because Delp, Aouni-Ateshian and Paul fail to teach or suggest, alone or in combination, all the limitations of the independent claims 1 and 10, the combination cannot make the claims obvious. Accordingly, claims 1 and 10 are allowable over Delp in view of Aouni-Ateshian and Paul. As claim 7 depends from claim 1, and claim 15 depends from claim 10, claims 7 and 15 are allowable over Delp in view of Aouni-Ateshian and Paul for at least the same reasons claims 1 and 10 are allowable, respectively.

The Office Action also rejects claims 4, 6, 8-9, 12, 14, 16-19, 21-22, 37-47, 51-57, 59-61, 64-78 and 80-86 as unpatentable over Delp in view of Aouni-Ateshian and Paul further in view of U.S. Patent No. 6,835,377 (Goldberg et al., hereinafter "Goldberg"). As noted above, Applicants have cancelled claims 4, 6, 8-9, 12, 14, 16-17, 37-47, 51-54, 64-65, 72-78 and 80-84. Thus, Applicants discuss this rejection only with regard to claims 18-19, 21-22, 55-57, 59-61, 66-71 and 85-86.

As dependent claims of claim 1, claims 55-57 and 59-61 also define a method to determine a therapy for joint disease, such method including, in part, electronically deriving information on the thickness or shape of at least one of articular cartilage and subchondral bone

to determine at least a portion of the geometry of an implant with at least a portion of the implant having a thickness similar to the thickness of normal articular cartilage adjacent to diseased articular cartilage. Accordingly, claims 55-57 and 59-61 are allowable over Delp, Aouni-Ateshian and Paul, alone or in combination, for at least the same reasons as discussed above with respect to claim 1. Similarly, as dependent claims of claim 10, claims 18-19, 21-22, 66-71 and 85-86 also define, in part, a method for determining therapy for joint disease including electronically deriving information on the thickness of articular cartilage, including normal and/or diseased articular cartilage, and selecting or designing a therapy wherein such therapy is an implant. Accordingly, claims 18-19, 21-22, 66-71 and 85-86 are allowable over Delp, Aouni-Ateshian and Paul, alone or in combination, for at least the same reasons as discussed above with respect to claim 10.

Additionally, Goldberg fails to teach the deficiencies of Delp, Aouni-Ateshian and Paul. Goldberg relates to a stem cell approach for cartilage regeneration. Goldberg does not teach or suggest anything related to the thickness of normal and/or diseased articular cartilage. Further, Goldberg does not teach or suggest anything related to the thickness of an implant, let alone an implant having a thickness similar to the thickness of normal articular cartilage adjacent to diseased articular cartilage. Accordingly, because Delp, Aouni-Ateshian, Paul and Goldberg fail to teach or suggest, alone or in combination, all the limitations of claims 18-19, 21-22, 55-57, 59-61, 66-71 and 85-86, the combination cannot make the claims obvious. Therefore, claims 18-19, 21-22, 55-57, 59-61, 66-71 and 85-86 are allowable over the combination.

The Office Action also rejects claims 20 and 58 as unpatentable over Delp in view of Aouni-Ateshian, Paul and Goldberg further in view of U.S. Patent No. 6,175,655 (George, III et al., hereinafter "George").

As a dependent claim of claim 1, claim 58 also defines a method to determine a therapy for joint disease, such method including, in part, electronically deriving information on the thickness or shape of at least one of articular cartilage and subchondral bone to determine at least a portion of the geometry of an implant with at least a portion of the implant having a thickness similar to the thickness of normal articular cartilage adjacent to diseased articular cartilage. Accordingly, claim 58 is allowable over Delp, Aouni-Ateshian and Paul further in view of Goldberg, alone or in combination, for at least the same reasons as discussed above with respect

to claims 18-19, 21-22, 55-57, 59-61, 66-71 and 85-86. Similarly, as a dependent claim of claim 10, claim 20 also defines, in part, a method for determining therapy for joint disease including electronically deriving information on the thickness of articular cartilage, including normal and/or diseased articular cartilage, and selecting or designing a therapy wherein such therapy is an implant. Accordingly, claim 20 is allowable over Delp, Aouni-Ateshian and Paul further in view of Goldberg, alone or in combination, for at least the same reasons as discussed above with respect to claims 18-19, 21-22, 55-57, 59-61, 66-71 and 85-86.

Additionally, George fails to teach the deficiencies of Delp, Aouni-Ateshian, Paul and Goldberg. To the extent that George relates to images, George does not teach or suggest anything related to the thickness of normal and/or diseased articular cartilage. Further, George does not teach or suggest anything related to the thickness of an implant, let alone an implant having a thickness similar to the thickness of normal articular cartilage adjacent to diseased articular cartilage. Accordingly, because Delp, Aouni-Ateshian, Paul, Goldberg and George fail to teach or suggest, alone or in combination, all the limitations of claims 20 and 58, the combination cannot make the claims obvious. Therefore, claims 20 and 58 are allowable over the combination.

CONCLUSION

All pending claims are believed to be in a form suitable for allowance. Therefore, the application is believed to be in a condition for allowance. The Applicants respectfully request early allowance of the application. The Applicants also request that the Examiner contact the undersigned, Karen A. Buchanan, if it will assist further examination of this application.

Applicants believe that a three month extension of time is required, and hereby request that the associated fees be charged to Deposit Account No. 19-4972. Applicants also request that any other fee required for timely consideration of this application be charged to Deposit Account No. 19-4972.

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Respectfully submitted,

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